

REMARKS

Claims 1, 3-6 and 21-24 are all the claims pending in the application. Claims 2, 7-20 and 25-36 have been canceled.

Claim 1 has been amended to incorporate the recitation of claim 2 and claim 2 has been canceled accordingly. In addition, claim 3 has been amended to revise the dependency from canceled claim 2 to claim 1, and claims 1 and 21 have been amended to delete the redundant phrase “at least a step of.” Accordingly, no new matter is added and entry of the Amendment is requested, respectfully.

A) Duplicate Claim

The Examiner asserted that claims 1-6 and 13-24 are duplicates of claims 7-12 and 25-36.

Claims 7-12 and 25-36 have been canceled, thus obviating this objection.

B) Claim Rejections - 35 U.S.C. § 102(b)

Claims 1, 5, 7, 13, 14, 21, 25 and 26 were rejected under 35 U.S.C. § 102(b) as being anticipated by Miller, *et al.* (U.S. Patent No. 6,383,344).

Claims 7, 13, 14, 25 and 26 have been canceled, thus making the rejection moot as to these claims.

In addition, claim 1 has been amended to incorporate the recitation of non-rejected claim 2. Thus, the rejection is overcome as to claim 1 and claim 5, which depends from claim 1.

As to claim 21, the Examiner asserted that Miller, *et al.* disclose a method for reducing the molecular weight of a polymer that comprises subjecting a solid phase polymer to a dose of gamma irradiation sufficient to permit the desired molecular weight reduction to occur, citing the

abstract. Further, the Examiner asserted that Miller, *et al.* discloses that the hyaluronic acid can have an initial molecular weight in the range of from about 1,000 kDa to about 3000 kDa, citing column 3, lines 6-12. The Examiner noted that this range overlaps the molecular weight range recited in claim 21.

For the following reasons, the rejection of claim 21 is traversed.

Claim 21 relates to a process for producing hyaluronic acid having a lowered molecular weight, which comprises irradiating an electron beam to a hyaluronic acid fraction. On the other hand, Miller, *et al.* disclose gamma irradiation or microwave irradiation for decreasing the molecular weight; however, Miller, *et al.* do not disclose electron beam irradiation for decreasing the molecular weight. Although both gamma rays and electron beams are a type of radiation, they are different. Gamma rays are electromagnetic radiation, whereas electron beams are particle beams. Also, an electron beam can be used more easily than gamma rays. Therefore, claim 21 is neither taught nor suggested by Miller, *et al.*

Furthermore, the hyaluronic acid fraction of claim 21 is in a liquid state. The present application demonstrates that the molecular weight can be lowered by electron beam irradiation even when the hyaluronic acid fraction to be used as the raw material is in a liquid state and that the molecular weight is apt to be lowered more in comparison to when the hyaluronic acid is in the solid state (cf. the paragraph bridging pages 19 and 20 in the present specification). Miller, *et al.* do not disclose such an advantage of the present invention. Therefore, claim 2 is also patentable over Miller, *et al.* on this ground.

C) Claim Rejections - 35 U.S.C. § 103(a)

Claims 1-36 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Miller, *et al.* (U.S. Patent No. 6,383,344).

The Examiner asserted that Miller, *et al.* shows that the basic process of irradiating polysaccharides or hyaluronic acid at a particular dosage is known in the art. The Examiner stated that the differences between Miller, *et al.* and the present claims is that the irradiation dosages taught by Miller, *et al.* are over a broader range than those recited in some of the claims. However, the Examiner asserted that it is within the skill of an artisan in this art to adjust the dosage of the electron beam in order to achieve optimum operation of the process.

For the following reasons, the rejection is traversed, respectfully.

Miller, *et al.* disclose gamma irradiation and microwave irradiation for decreasing the molecular weight; however, Miller, *et al.* neither disclose nor suggest electron beam irradiation for the decrease as disclosed in the present application.

The attached Fig. 1 shows the relationship between the results of a decrease in the molecular weight of hyaluronic acid with gamma irradiation shown in Table 1 (Lots A-C) of Miller, *et al.* and those of GAG having a weight average molecular weight of 5,000 to 70,000 with electron beam irradiation shown in Table 2 of the present application. The ordinate shows the molecular weight and the abscissa shows the irradiation dose. Thus, the equation now recited in claim 1 and its specific ranges (e.g., the weight average molecular weight of 5,000 to 70,000 and the range of “a”) in the decrease of the molecular weight by electron beam irradiation are neither taught nor suggested by Miller, *et al.* Therefore, claims 1 and 3 to 6 are not made obvious over Miller, *et al.*

Also, Miller, *et al.* disclose that the method is applied to the polymer in the solid phase. On the other hand, the method of claim 21 in the present application is applied to a hyaluronic acid fraction in a liquid state. The attached Fig. 2 shows the relationship between the results of the decrease in the molecular weight of hyaluronic acid in a solid state with electron beam irradiation and those of hyaluronic acid in a liquid state. The ordinate shows the molecular weight and the abscissa shows the irradiation dose. Based on Fig. 2 and the specification of the present application, it can be seen that the decrease of the molecular weight of hyaluronic acid is accelerated by electron beam irradiation for hyaluronic acid in a liquid state in comparison with hyaluronic acid in a solid state. This effect is not taught or suggested by Miller, *et al.* Therefore, claims 21 to 24 are not made obvious over Miller, *et al.*

In view of the above remarks the Examiner is requested, respectfully, to reconsider and remove this rejection.

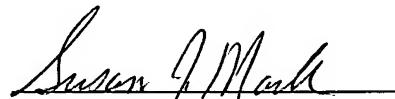
In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

AMENDMENT UNDER 37 C.F.R. § 1.111
U.S. Patent Application No.: 10/755,667

Attorney Docket No.: Q79414

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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